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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
POURBOHLOUL, SARIRA CAMILLA	

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
12/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,785	LAULICHT ET AL.	
	Examiner	Art Unit	
	S. Camilla Pourbohloul	1765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 50-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to the election made without traverse of restricted claims 1-23 and 50-61 (Group I) filed in a timely manner on September 30, 2010.

Claims 24-42 and 43-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups II and III respectively, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 19 recite the limitation "the coating" in line 2. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b)/103(a) that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-10, 15-20, 50-61 are rejected under 35 U.S.C. 102(b) as being anticipated, or in the alternative, under 35 U.S.C. 103(a) as obvious over Gaserod et al. (US 6,165,503).

Regarding claims 1-6, 52-56, and 59, Gaserod et al. teaches a population of microcapsules comprising a blend of capsules with different membrane thicknesses (i.e. shell thicknesses) in order to provide a pulsed release of the encapsulated drug (corresponds to the varied diffusion characteristics of the instant claims) (col. 6, lines 40-43), wherein the standard deviation of capsule diameter is 3-6% of the mean (col. 7, lines 26-30). Further, the microcapsules are spherical particles with diameter of 200 to 700 μm (col.6, lines 44-49). Although, Gaserod is silent with respect to the microcapsule volume as recited in the instant claims, however, in view of the fact that the microcapsules of Gaserod et al. have substantially the same particle diameter as that recited in the instant claims, and since volume is directly related to particle diameter, a reasonable basis exists to believe that compositions of Gaserod et al., exhibit substantially the same interior volume. Therefore, the microcapsule of Gaserod would

inherently be the same as the claimed microstructures. See MPEP 2112.01(I) , *In re Best*, 562 F2d at 1255, 195 USPQ at 433, *Titanium Metals Corp v Banner*, 778 F2d 775, 227 USPQ 773 (Fed Cir 1985), *In re Ludtke*, 441 F2d 660, 169 USPQ 563 (CCPA 1971) and *Northam Warren Corp v D F Newfield Co*, 7 F Supp 773

It is the examiner's position that the person of ordinary skill in the art would have found it obvious to make a uniform population of microcapsules displaying low standard deviation for microcapsule volume to form uniformly sized population with improved rheological and delivery characteristics.

Although, Gaserod is silent with regard to the continuous and sigmoidal pattern of shell thickness variation and drug diffusion in the microcapsule population, Gaserod recognizes the importance of microcapsule membrane thickness and more specifically teaches that capsules with thin membrane layers are used for masking unpleasant taste and capsules with thick layers are used for adhesion to a target site. (col. 6, lines 30-38). Additionally, Gaserod teaches that choice of membrane thickness can be modified according to the desired end use for example, the capsule population of its invention contains capsules with different membrane thicknesses in order to obtain a sustained or pulsed release or diffusion of the active material. Therefore, it is reasonable to believe that the variation in drug release or diffusion disclosed by Gaserod would inherently be the same as the claimed variation pattern because the design of the microcapsule population shell thickness could be simply manipulated by combining microcapsules of specific thicknesses based on the desired release pattern of the active material. Accordingly, a person of ordinary skill in the art would have found it obvious to provide

different populations of various shell thicknesses in order to achieve pulsed- or controlled-release of the drug.

Regarding claims 9, 10, 50 and 51, Gaserod teaches porous microcapsule membrane (col. 6, lines 1-29) comprising of a polycationic polysaccharide (i.e. chitosan), a polyanionic polysaccharide (i.e. alginate) (col. 3, lines 28-43), and a crosslinking agent such as calcium (col. 7, lines 18-23; col. 8, lines 45-48).

Regarding claims 57, 58, 60, and 61, Gaserod teaches the microcapsules carrying an active agent such as pharmaceutically active drug, living or dead cells or seeds (col. 5, lines 40-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-23, and 50-61, are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaserod et al. (US 6,165,503) in view of Ipponamatsu et al. (US 5,376,347).

Regarding claims 1-6, 52-56, and 59, Gaserod et al. teaches a population of microcapsules comprising a blend of capsules with different membrane (i.e. shell) thickness in order to provide a pulsed release (i.e. diffusion characteristics of capsule) of the encapsulated drug (col. 6, lines 40-43), wherein the standard deviation of capsule diameter is 3-6% of the mean (col. 7, lines 26-30). Although, Gaserod is silent with respect to the microcapsule volume as recited in the instant claims, however, in view of the fact that the microcapsules of the prior art have substantially the same particle diameter as that recited in the instant claims, and since volume is directly related to particle diameter, a reasonable basis exists to believe that compositions of White et al., exhibit substantially the same volume. Therefore, the microcapsule of Gaserod would inherently be the same as the claimed microstructures. See MPEP 2112.01(I) , *In re Best*, 562 F2d at 1255, 195 USPQ at 433, *Titanium Metals Corp v Banner*, 778 F2d 775, 227 USPQ 773 (Fed Cir 1985), *In re Ludtke*, 441 F2d 660, 169 USPQ 563 (CCPA 1971) and *Northam Warren Corp v D F Newfield Co*, 7 F Supp 773

It is the examiner's position that the person of ordinary skill in the art would have found it obvious to make a uniform population of microcapsules displaying low standard deviation of volume in order to maximally and efficiently enclose or encapsulate particles of a specific size.

Regarding claims 7, 8, 11-14, Gaserod et al. fails to teach microcapsules having a volume of less than 10nL which according to Applicant's specification correspond to microcapsules of 1-50 μm in diameter [0033]. Hence attention is directed to the microcapsules of Ipponamatsu et al. In the same field of endeavor, Ipponamatsu teaches microspheres with particle size of 0.01 to 500 μm (col. 2, lines 8-29) and with a volume-based standard deviation of less than or equal to 10% (col. 4, lines 62-67). While, Ipponamatsu does not explicitly disclose the volume of its microsphere, it is reasonable to believe that since the volume of a sphere is a function of its diameter, the microspheres of Ipponamatsu clearly exhibit the same volumetric values. Ipponamatsu et al. teaches that its microsphere preparation is superior to the prior arts microspheres with respect to its size and lower standard deviation and hence demonstrate improved performance in applications such as colored additives in cosmetics and ink, or sustained release of perfumes, dyes, vitamins and drugs (col. 7, lines 1-17). Therefore, it would have been obvious to one skilled in the art at the time of the invention to provide the size characteristics of Ipponamatsu to microcapsule preparation of Gaserod in order to improve the flow and consistency of encapsulated smaller compounds and molecules in miniature applications.

Regarding claims 9, 10, 15-19, 50 and 51, Gaserod teaches a porous microcapsule (col. 6, lines 1-29) comprising of a polycationic polysaccharide (i.e. chitosan), a polyanionic polysaccharide (i.e. alginate) (col. 3, lines 28-43), and a crosslinking agent such as calcium (col. 7, lines 18-23; col. 8, lines 45-48).

Regarding claims 20-23, 57, 58, 60, and 61, Gaserod teaches the microcapsules carrying an active agent such as pharmaceutically active drug, living and dead cells or seeds (col. 5, lines 40-52).

Claim Rejections - 35 USC § 103

Claims 1-7, 9-13, 21-23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. (US 6,596,310) in view of Amsden et al. (US 6,224,794) .

Chou et al. teaches time-release membrane capsules containing sperm cells and other active ingredients as an energy source for sperm, wherein the capsule membranes vary in thickness and thus allow for sustained-release of sperm from the capsules (col. 9, lines 11-25). The capsule membrane comprises gel forming polymers including sodium alginate, chitosan, guar gum and pectin or their mixtures (col. 3, lines 55-63; col. 4, lines 38-63). While Chou does not explicitly teach the continuous and sigmoidal pattern of shell thickness variation and drug diffusion in its microcapsule population, it is reasonable to believe that the variation in diffusion or drug release of Chou is inherently the same as the claimed variation pattern, for the reason that the design of the microcapsule population shell thickness could be simply manipulated by combining microcapsules of specific thicknesses based on the desired release pattern of the active material.

Chou fails to teach microcapsules with the size, volume and standard deviation as recited in the instant claims. Hence attention is directed to Amsden et al. in the same field of endeavor, Amsden teaches a uniformly sized population of microspheres

comprising chitosan-alginate shells (col. 6, lines 14-35) with an average diameter of 50-150 μm (col. 4, lines 35-48) and a standard deviation of between 5-15% (col. 8, lines 14-25, Example 1 and Example 2).

Claim Rejections - 35 USC § 103

Claims 1-7, 9-13, 21-23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. (US 6,596,310) in view of Ipponamatsu et al. (US 5,376,347) .

Chou et al. teaches time-release membrane capsules containing sperm cells and other active ingredients as an energy source for sperm, wherein the capsule membranes vary in thickness and thus allow for sustained-release of sperm from the capsules (col. 9, lines 11-25). The capsule membrane comprises gel forming polymers including sodium alginate, chitosan, guar gum and pectin or their mixtures (col. 3, lines 55-63; col. 4, lines 38-63). While Chou does not explicitly teach the continuous and sigmoidal pattern of shell thickness variation and drug diffusion in its microcapsule population, it is reasonable to believe that the variation in diffusion or drug release of Chou is inherently the same as the claimed variation pattern, for the reason that the design of the microcapsule population shell thickness could be simply manipulated by combining microcapsules of specific thicknesses based on the desired release pattern of the active material.

Although Chou fails to teach microcapsules with the size, volume and standard deviation as recited in the instant claims, however, Ipponamatsu et al. teaches microspheres teaches microspheres with particle size of 0.01 to 500 μm (col. 2, lines 8-29) and with a volume-based standard deviation of less than or equal to 10% (col. 4, lines 62-67). While, Ipponamatsu does not explicitly disclose the volume of its microsphere, it is reasonable to believe that since the volume of a sphere is a function of its diameter, the microspheres of Ipponamatsu display the same volumetric values as that of the instant claims. Ipponamatsu et al. teaches that its microsphere preparation is superior to the prior arts microspheres with respect to its size and low volume standard deviation and hence demonstrate improved performance in applications such as colored additives in cosmetics or ink, or sustained release of perfumes, dyes, vitamins and drugs (col. 7, lines 1-17). Therefore, it would have been obvious to one skilled in the art at the time of the invention to provide the size characteristics of Ipponamatsu to microcapsule preparation of Gaserod in order to improve the flow and consistency of encapsulated small compounds and molecules in miniature applications.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Camilla Pourbohloul whose telephone number is (571)270-7744. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James Seidleck/
Supervisory Patent Examiner, Art Unit 1765

/SCP/